

Submission Number: 17290

3/13/2008 8:42:17 PM

FWA Number: FWA00006253

Institution Name: LAWRENCE BERKELEY NATL LAB

OMB No. 0990-0278

Approved for use through 1/31/2008

U.S. Department of Health and Human Services (DHHS)
Federalwide Assurance (FWA) for the Protection of Human Subjects
For Domestic (U.S.) Institutions

1. Institution Filing Assurance

Legal Name: LAWRENCE BERKELEY NATL LAB

City: BERKELEY

State: CA

DHHS Institutional Profile Code: 577512

Federal Entity Identification Number (EIN): 942951741

This Assurance replaces:

2. Institutional Components

List below all components over which the Institution has legal authority that operate under a different name. Also list with an asterisk (*) any alternate names under which the Institution operates. The Institution should have available for review by the Office for Human Research Protections (OHRP) upon request a brief description and line diagram explaining the interrelationships among the Assurance Signatory Official, the Institutional Review Board (IRB), IRB support staff, and investigators in these various components.

NOTE: The Signatory Official signing this Assurance must be legally authorized to represent the Institution providing this Assurance and all components listed below. Entities that the Signatory Official

is not legally authorized to represent may not be listed here without the prior approval of OHRP.

Name of Component or Alternate Names Used	City, State (or Country if Outside U.S.)
---	--

BERKELEY, LBNL	BERKELEY, CA
----------------	--------------

Submission Number: 17290

3/13/2008 8:42:17 PM

FWA Number: FWA00006253

Institution Name: LAWRENCE BERKELEY NATL LAB

OMB No. 0990-0278

Approved for use through 1/31/2008

3. Statement of Principles

This Institution assures that all of its activities related to human subjects research, regardless of funding source, will be guided by the ethical principles in the following documents:

THE BELMONT REPORT

4. Applicability:

(a) This Institution assures that whenever it engages in human subjects research conducted or supported by any federal department or agency that has adopted the Federal Policy for the Protection of Human Subjects, known as the Common Rule, the Institution will comply with the Terms of the Federalwide Assurance for Institutions Within the United States (contained in a separate document on the OHRP website), unless the research is otherwise exempt from the requirements of the Common Rule or a department or agency conducting or supporting the research has determined that the research shall be covered by a separate assurance.

(b) Optional: This Institution elects to apply the following to all of its human subjects research regardless of the source of support, except for research that is covered by a separate assurance:

The Common Rule and subparts B, C, and D of the HHS regulations at 45 CFR part 46

5. Designation of Institutional Review Boards (IRBs)

This Institution designates the following IRB(s) for review of research under this Assurance (if the IRB has not previously registered with HHS or has not provided a membership roster to HHS, please submit to OHRP the appropriate IRB registration materials which are available on the OHRP website).

NOTE: Reliance on the IRB of another institution or organization or an independent IRB must be documented by a written agreement that is available for review by OHRP upon request. OHRP's sample IRB Authorization Agreement may be used for this purpose, or the parties involved may develop their own agreement. Future designation of other IRBs requires an update of the FWA.

HHS IRB Registration Number	Name of IRB As Registered with HHS
IRB00000172	U OF CALIFORNIA LOS ANGELES-MIRB1 GENERAL BIOMEDICAL IRB #1 - GENERAL BIOMEDICAL
IRB00000173	U OF CALIFORNIA LOS ANGELES-MIRB2 CANCER/INFECTIOUS DISEASE IRB #2
IRB00000174	U OF CALIFORNIA LOS ANGELES-NORTH GENERAL SOCIAL-BEHAVIOR IRB #3
IRB00000195	U OF CALIFORNIA RIVERSIDE IRB #1
IRB00000229	PARNASSUS COMMITTEE IRB #1
IRB00000230	SAN FRANCISCO GENERAL HOSP (SFGH) COMMITTEE IRB #2
IRB00000266	U CALIFORNIA SANTA CRUZ IRB #1
IRB00000307	U CALIFORNIA SANTA BARBARA IRB #1

Submission Number: 17290

3/13/2008 8:42:17 PM

FWA Number: FWA00006253

Institution Name: LAWRENCE BERKELEY NATL LAB

OMB No. 0990-0278

Approved for use through 1/31/2008

IRB00000353	U OF CALIFORNIA SAN DIEGO IRB #1B - COMMITTEE B
IRB00000354	U OF CALIFORNIA SAN DIEGO IRB #1A - COMMITTEE A
IRB00000355	U OF CALIFORNIA SAN DIEGO IRB #2 - COMMITTEE S
IRB00000393	U OF CALIFORNIA, IRVINE IRB #1 COMMITTEE A
IRB00000394	U OF CALIFORNIA, IRVINE IRB #2 COMMITTEE B
IRB00000395	U OF CALIFORNIA, IRVINE IRB #3 COMMITTEE C
IRB00000425	CLINICAL COMMITTEE A - UC DAVIS
IRB00000426	CLINICAL COMMITTEE B - UC DAVIS
IRB00000455	U OF CALIFORNIA BERKELEY IRB #1 - CPHS-I
IRB00002758	U OF CALIFORNIA SAN DIEGO IRB #4 - COMMITTEE C
IRB00003023	SOCIAL AND BEHAVIORAL COMMITTEE -C, UC DAVIS
IRB00003471	LAUREL HEIGHTS COMMITTEE(LHTS) IRB #3
IRB00004473	U OF CALIFORNIA LOS ANGELES-NEUROSCIENCE MIRB3 IRB #4
IRB00004474	U OF CALIFORNIA LOS ANGELES-SOUTH GENERAL IRB #5
IRB00005096	U OF CALIFORNIA SAN FRANCISCO IRB #4 - MT. ZION
IRB00005610	U OF CALIFORNIA BERKELEY IRB #2 - CPHS-II
IRB00006282	UNIVERSITY OF CALIFORNIA, MERCED IRB #1
IRB00006447	LAWRENCE BERKELEY NATIONAL LABORATORY IRB #1

6. Human Protections Administrator (e.g., Human Subjects Administrator or Human Subjects Contact Person)

First Name: CHRISTINE

Middle Initial: E

Last Name: BYRNE

Degrees or Suffix (e.g., MD, PhD): MA, CIP

Institutional Title: LEAD COMPLIANCE SPECIALIST, HUMAN & ANIMAL RESEARCH

Institution: LAWRENCE BERKELEY NATL LAB

Telephone: (510) 486-5507

FAX: (510) 486-5499

E-mail: CEBYRNE@LBL.GOV

Address: 1 CYCLOTRON ROAD

MS 26R0143

City: BERKELEY

State: CA

Zip Code: 94720

NOTE: Institutions operated by the U.S. Government may need to obtain department or agency clearance prior to submission of the FWA to OHRP. Please contact the relevant department or agency Human Subject Protections Officer before forwarding this Assurance to OHRP.

Submission Number: 17290

3/13/2008 8:42:17 PM

FWA Number: FWA00006253

Institution Name: LAWRENCE BERKELEY NATL LAB

OMB No. 0990-0278

Approved for use through 1/31/2008

7. Signatory Official (i.e., Official Legally Authorized to Represent the Institution

-- cannot be IRB Chairperson or IRB member)

I understand that the Assurance Training Modules on the OHRP website describe the responsibilities of the Signatory Official, the IRB Chair(s), and the Human Protections Administrator under this Assurance. Additionally, I recognize that providing research investigators, IRB members and staff, and other relevant personnel with appropriate initial and continuing education about human subject protections will help ensure that the requirements of this Assurance are satisfied.

Acting officially in an authorized capacity on behalf of this Institution and with an understanding of the Institution's responsibilities under this Assurance, I assure protections for human subjects as specified above. The IRB(s) designated above are to provide review for all research to which this Assurance applies. The designated IRB(s) will comply with the Terms of the Federalwide Assurance for Institutions Within the United States and possess appropriate knowledge of the local context in which this Institution's research will be conducted.

All information provided with this Assurance is up-to-date and accurate. I am aware that false statements could be cause for invalidating this Assurance and may lead to other administrative or legal action.

Signature:  Date: 3/24/08
Joe W Gray

First Name: JOE

Middle Initial: W

Last Name: GRAY

Degrees or Suffix (e.g., MD, PhD): PHD

Institutional Title: ASSOCIATE LAB DIRECTOR, LIFE & ENVIRONMENTAL SCIENCES

Institution: LAWRENCE BERKELEY NATL LAB

Telephone: (510) 495-2438

FAX: (510) 495-2535

E-mail: JWGRAY@LBL.GOV

Address: 1 CYCLOTRON ROAD
MS 977R225A

City: BERKELEY

State: CA

Zip Code: 94720